

### **REMARKS**

Claims 1, 3, 5, 7-15, 17-22 and 25-31 and 33-36 were pending in this application. Claims 1, 3, 5, 7-15, 17 and 18 were withdrawn and claims 19-22, 25-31 and 33-36 were under examination. Claims 3, 7, 8, 26, 27 and 29 are canceled herein. Thus, after entry of this amendment, **claims 1, 5, 9-15, 17-22, 25, 28, 30, 31 and 33-36 will be pending in this application, and claims 19-22, 25, 28, 30, 31 and 33-36 will be under examination.**

Claims 5, 9, 11, 19, 25 and 28 are amended to remove the phrase "or variant of the fragment." Claims 5, 9, 25 and 28 are further amended to remove reference to conservative amino acid substitutions. Applicants reserve the right to file one or more continuing applications directed to the canceled subject matter.

No new matter has been introduced by these amendments. Applicants submit the amendments provided herein place the application in better condition for allowance and thus should be entered.

### **INFORMATION DISCLOSURE STATEMENT**

The Information Disclosure Statement (IDS) filed April 22, 2005 in connection with this application does not appear to have been considered by the Examiner. Provided with this Amendment and Response is a copy of the Form 1449 submitted with the IDS of April 22, 2005. Applicants request that the references be made of record in the application and that the signed Form 1449 be returned to Applicants.

### **REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH**

**Claims 19-22, 25-31 and 33-36** remain rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement for the reasons of record. Applicants note the Office states claims 19-23 and 25-36 are rejected; however, claims 23 and 32 were canceled in the Amendment and Response filed July 24, 2007. Thus, Applicants believe claims 19-22, 25-31 and 33-36 are currently rejected under 35 U.S.C. §112, first paragraph. Claims 26, 27 and 29 are canceled herein, rendering the rejection moot as it pertains to these claims. Applicants traverse this rejection as it pertains to claims 19-22, 25, 28, 30, 31 and 33-36.

The Office maintains that the disclosure does not provide an adequate written description for claims directed to fragments of thymosin  $\beta_4$ , wherein the fragment comprises 0 to 5 conservative

amino acid substitutions in comparison to SEQ ID NO: 1. Although Applicants disagree with this conclusion, solely in an effort to advance prosecution, claims 19, 25 and 28 are amended to remove the phrase “or variant of a fragment” and claims 25 and 28 are further amended to exclude polypeptides comprising 0 to 5 conservative amino acid substitutions.

Accordingly, Applicants request withdrawal of this rejection under 35 U.S.C. §112, first paragraph.

### **REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH**

**Claims 19-22 and 25-31** stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Office maintains that it is not clear how a peptide can have the amino acid sequence of SEQ ID NO: 1 and have substitutions. Claims 19-22, 30 and 31 are not directed to polypeptides comprising amino acid substitutions in comparison to SEQ ID NO: 1, thus Applicants submit it is improper to include these claims in the current rejection. Claims 26, 27 and 29 are canceled herein, rendering the rejection moot as it pertains to these claims.

In regard to claims 25 and 28, Applicants disagree with the Office’s conclusion; however, solely in an effort to advance prosecution, claims 25 and 28 are amended herein to exclude polypeptides comprising amino acid substitutions in comparison to SEQ ID NO: 1. Accordingly, Applicants request withdrawal of this rejection under 35 U.S.C. §112, second paragraph.

### **REJECTION UNDER 35 U.S.C. §102**

**Claims 19-22, 25-31 and 33-36** remain rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Kleinman *et al.* (WO 00/06190) for the reasons of record. Claims 26, 27 and 29 are canceled herein, rendering the rejection moot as it pertains to these claims. Applicants traverse the rejection as it pertains to claims 19-22, 25, 28 and 33-36.

First, Applicants note that although the Office indicates claims 33-36 are included in the instant rejection, the subject matter of these claims is not addressed in the pending Office action, nor was it addressed in the Office action dated May 30, 2007. Furthermore, claims 33-36 are directed to compositions for promoting hair growth comprising a polypeptide consisting of specific amino acid sequences of SEQ ID NO: 1, none of which are disclosed by Kleinman *et al.* Therefore, Applicants submit claims 33-36 are not anticipated by Kleinman *et al.*

In regard to claims 19-22, 25 and 28, Applicants submit that Kleinman *et al.* does not teach each and every element of the claims, and thus does not anticipate these claims. In response to Applicants arguments submitted July 24, 2007, the Office states on page 8 of the Office action that “Kleinman *et al.* discloses a composition containing a polypeptide comprising the amino acid sequence LKKTET and conservative variants thereof.” Applicants do not dispute that Kleinman *et al.* teaches polypeptides *comprising* LKKTET. However, Kleinman *et al.* do not teach polypeptides “no more than 10 amino acid residues in length,” nor do Kleinman *et al.* teach polypeptides for promoting hair growth as claimed herein. In order for a reference to anticipate a claim, the reference must teach each and every element of the claim. Since Kleinman *et al.* does not teach each and every element of claims 19-22, 25 and 28, the claims are not anticipated. Accordingly, Applicants request withdrawal of this rejection under 35 U.S.C. §102(b).

## DOUBLE PATENTING

**Claims 19-22, 25-31 and 33-36** stand rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 3-5 and 29 of U.S. Pre-Grant Publication No. 2004/0220111 for the reasons of record. Claims 26, 27 and 29 are canceled herein, rendering the rejection moot as it pertains to these claims. Applicants traverse this rejection as it pertains to claims 19-22, 25, 28, 30, 31 and 33-36.

Applicants note that U.S. 2004/0220111 contains only 26 claims in the published document. Therefore, it is unclear to Applicants exactly which claims the Office intended to include in this rejection. In addition, as summarized in the Amendment and Response filed July 24, 2007, U.S. Pre-Grant Publication No. 2004/0220111 contains the same disclosure as Kleinman *et al.*, cited above in regard to the rejection under 35 U.S.C. §102(b). Kleinman *et al.* do not claim or even suggest polypeptides of no more than 10 amino acid residues in length, nor any fragments of the thymosin  $\beta_4$  polypeptide. Kleinman *et al.* also do not claim or teach any compositions for promoting hair growth in a subject. Furthermore, Kleinman *et al.* do not claim or teach any of the specific polypeptides recited in claim 33.

Thus, Applicants submit the pending claims are patentably distinct from the claims of U.S. Pre-Grant Publication No. 2004/0220111 and request withdrawal of the double patenting rejection.

### CONCLUDING STATEMENT

It is respectfully submitted that the present claims are in a condition for allowance. Should the Examiner have further questions or comments with respect to examination of this case, it is requested that the Examiner telephone the undersigned so that further examination of this application can be expedited.

Respectfully submitted,

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